IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

JACOB HOBUS, Plaintiff, v. HOWMEDICA OSTEONICS CORPORATION, Defendant.	Case No.: 3:21-cv-00080-AN OPINION AND ORDER

Plaintiff Jacob Hobus filed this action against defendant Howmedica Osteonics Corporation in Multnomah County Circuit Court, alleging strict products liability, breach of express warranty, breach of implied warranty, and negligence. Defendant subsequently removed the case to this Court on January 19, 2021, under diversity jurisdiction.

On February 6, 2023, plaintiff filed a Motion for Partial Summary Judgment. Between February 7, 2023 and February 8, 2023, defendant filed an Amended Motion in limine to Exclude Testimony of Dr. Johnson, an Amended Motion in limine to Exclude Testimony of Truman, a Motion in limine to Exclude Testimony of Cary, and its own Motion for Summary Judgment. Oral argument on all five motions was held on July 24, 2023. For the foregoing reasons, plaintiff's Motion for Partial Summary Judgment is DENIED, defendant's Amended Motion in limine to Exclude Testimony of Dr. Johnson is GRANTED, defendant's Amended Motion in limine to Exclude Testimony of Truman is GRANTED in part and DENIED in part, defendant's Motion in limine to Exclude Testimony of Cary is DENIED, and defendant's Motion for Summary Judgment is GRANTED.

LEGAL STANDARD

A. Motions in Limine

Defendant bases each of its motions in limine on Federal Rule of Evidence ("FRE") 702, which states:

> "A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> "(b) the testimony is based on sufficient facts or data;
> "(c) the testimony is the product of reliable principles and methods; and
> "(d) the expert has reliably applied the principles and methods to the facts of the case."

B. Motion for Summary Judgment

Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). When deciding a motion for summary judgment, the court construes the evidence in the light most favorable to the non-moving party. *See Barlow v. Ground*, 943 F.2d 1132, 1135 (9th Cir. 1991). When cross-motions for summary judgment are filed, each party's evidence is considered, "regardless under which motion the evidence is offered." *Las Vegas Sands, LLC v. Nehme*, 632 F.3d 526, 532 (9th Cir. 2011). However, "the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The substantive law determines which facts are material. *Id.* at 248. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Id.* A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

The moving party has the initial burden of informing the court of the basis for its motion and identifying the portions of the pleadings and the record that it believes demonstrate the absence of an issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Where the non-moving party bears the burden of proof at trial, the moving party need not produce evidence negating or disproving every essential element of the non-moving party's case. *Id.* at 325. Instead, the moving party need only prove that there is an absence of evidence to support the non-moving party's case. *Id.*; *see In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010). If the moving party sustains its burden, the

non-moving party must then show that there is a genuine issue of material fact that must be resolved at trial. *Celotex*, 477 U.S. at 324.

BACKGROUND

Because the Court is reviewing cross-motions for summary judgment, the undisputed facts are provided neutrally, but construed in the light most favorable to each respective party when considering their motions. This case arises from a lumbar spine surgery performed on plaintiff in which an AccuLIF TL expandable interbody fusion cage device was implanted in plaintiff's spine. The cage subsequently collapsed, and plaintiff underwent revision surgery to adjust the device.

Plaintiff has a history of chronic back and leg pain that worsened after a motor vehicle collision in June 2014. Def.'s Mot. for Summ. J., ECF [35], Ex. A, at 3-4. Plaintiff began seeing Dr. Jeffrey Johnson on April 11, 2016 for constant and severe back and leg pain. *Id.* at 6. Plaintiff reported pain traveling across his back and into his hips and legs on the left side, as well as numbness and tingling in his foot and toes. *Id.* Narcotic medications, physical therapy, and injections were unsuccessful in treating plaintiff's pain. *Id.* On May 10, 2016, Dr. Johnson performed a bilateral L4-L5 decompression and fusion surgical operation, including transforaminal lumbar interbody fusion. *Id.* at 4. During this surgery, an AccuLIF TL device was implanted in plaintiff's spine in the L4-L5 space. *Id.* Ex. D, at 3.

Following the surgery, Dr. Johnson's office compiled notes on plaintiff's post-operative visits. In plaintiff's post-operative visit on June 10, 2016, Dr. Johnson's medical notes stated, "It is not clear whether [plaintiff's] symptoms have really improved, he is somewhat equivocal about this" and that plaintiff "is taking slightly less pain medicine now than he was during his hospital stay." *Id.* at 5. In plaintiff's post-operative visit on August 24, 2016, Dr. Johnson's medical notes stated, "Although [plaintiff] expresses satisfaction with the results of the surgery, he does not appear to be doing very well overall. He relates that his back and leg pain and his leg tingling is better, but he still has constant severe headaches and neck pain." *Id.* at 7. Further, Dr. Johnson stated, "I suspect that [plaintiff's] pain issues are much larger than what we dealt with, with his back surgery. . . . I do not know if there is anything that is going to accelerate his return to a more normal lifestyle for a young person." *Id.* In plaintiff's post-

operative visit on April 20, 2017, Dr. Johnson wrote, "There has been little change in [plaintiff's] overall pain picture. He still has left-sided back and leg pain, which is fairly diffuse. He is also complaining of neck pain that travels to his left shoulder." *Id.* at 8.

On June 29, 2017, plaintiff received a cervical spine MRI and a lumbar spine MRI at Dr. Johnson's office. *Id.* at 10-17. On July 10, 2017, Dr. Johnson reviewed the images with plaintiff and sent a letter to plaintiff's primary physician, Dr. Lindsey Wismer. *Id.* at 18-19. In the letter, Dr. Johnson stated, "[Plaintiff's] surgery was unremarkable, and he seemed to recover from it reasonably well. Unfortunately, he has never had much relief in terms of his overall pain level." *Id.* at 18. Further, Dr. Johnson stated that "[t]he follow-up MRI scan of the lumbar spine and the new MRI of the cervical spine are both fairly unremarkable. . . . There is no cord compression or nerve root impingement in any location. There is nothing there to account for his neck pain or his arm or hand symptoms." *Id.* Dr. Johnson also noted that the interbody cage "looks to be positioned as it was at the time of surgery. There is no neural impingement." *Id.* Dr. Johnson concluded that "further surgery would not be helpful" and that plaintiff's pain was "associated with poor outcome from surgery." *Id.* at 19.

On November 21, 2018, Dr. Johnson sent another letter to Dr. Wismer. Dr. Johnson noted that, when he saw plaintiff in July 2017, plaintiff "noted at that time that his pain had essentially returned to where it was before the surgery." *Id.* at 20. Dr. Johnson stated that, after reviewing the MRI scans in July 2017, he saw "no obvious problems there or explanations as to why [plaintiff] was having symptoms." *Id.* Dr. Johnson noted that plaintiff had received a second opinion from a spine surgeon at OHSU, where he received additional imaging, including x-rays and a CT scan. However, Dr. Johnson acknowledged that "[t]he surgeons at OHSU did not recommend further surgery." *Id.* at 21. Dr. Johnson highlighted that plaintiff's "pain ha[d] continued to worsen" and that "[i]t follow[ed] much the same pattern as it always ha[d]." *Id.* Dr. Johnson noted that, "[t]here [was] no pattern to [plaintiff's] symptoms" and that plaintiff "ha[d] never been able to return to [ ] work since the surgery." *Id.* Regarding the 2017 MRI scans, Dr. Johnson stated that the AccuLIF TL cage "appears to be properly positioned" and stated that the x-rays and CT scan performed at OHSU in 2017 also "showed the

hardware in good position, without evidence of loosening or halo."[1] *Id.* at 23. Further, Dr. Johnson acknowledged that OHSU physicians had told plaintiff that "his pain was related to issues such as hardware migration, lack of fusion, or left pedicle screw at L4 going through the facet joint," but stated that he "strongly suggest[ed] that this [was] not the source of [plaintiff's] ongoing pain" and reiterated that he "[did] not see on the studies that we have any evidence of hardware migration." *Id.* at 24. Dr. Johnson stated, "His pain is still present in exactly the same pattern as it was before the surgery, and in fact, going back for many years. . . . [Failure to eliminate symptoms] is an all too familiar result of back surgery, even when the surgery is otherwise uncomplicated." *Id.* Ultimately, Dr. Johnson recommended additional x-rays and MRI scans. *Id.* at 24-25.

The additional imaging was taken on December 7, 2018. *Id.* at 26-27. On December 13, 2018, Dr. Johnson met with plaintiff regarding the new imaging and wrote a letter to Dr. Wismer. *Id.* at 28. In the letter, Dr. Johnson noted that there was what "appear[ed] to be a solid fusion at L4-5[,]" "there ha[d] been a change in the interbody cage compared with the preoperative study" and that "the foot plate [was] no longer extended," which suggested "that the hydraulic mechanism failed in some way." *Id.* However, Dr. Johnson stated that that finding was "of questionable significance." *Id.* Further, Dr. Johnson noted that the MRI scan "did not suggest that there [was] any neural impingement in any location, particularly at the L4-5 level." *Id.* Dr. Johnson acknowledged that plaintiff could undergo reoperative surgery but felt "fairly strongly . . . that the likelihood of this alleviating [plaintiff's] pain [was] low." *Id.*

On January 31, 2019, Dr. Johnson again met with plaintiff. *Id.* at 31. In his notes, Dr. Johnson noted that plaintiff's pain returned in the spring and summer of 2017, but "[i]maging at that time was unrevealing" and plaintiff's "pain continued to worsen." *Id.* Dr. Johnson concluded by noting that plaintiff was admitted for re-operative surgery to "attempt to remove or reposition the interbody cage at L4-L5." *Id.* at 32.

[1] In his deposition, Dr. Johnson stated that, after reviewing this imaging again while making his expert report, these scans did indicate that the cage had collapsed. Def.'s Amended Mot. in limine to Exclude Testimony of Dr. Johnson, ECF [37], Ex. C, at 115:3-22.

The re-operative surgery occurred on February 22, 2019. *Id.* at 34-38. Through office visits from April 11, 2019 through March 5, 2021, Dr. Johnson frequently noted plaintiff's progress and improvement, albeit with some setbacks during the COVID-19 pandemic. *Id.* at 39-57. Dr. Johnson reviewed post-operative x-rays several times and indicated each time that there had been no changes in the interbody cage following the revision surgery. *Id.* at 43, 50, 52. On July 2, 2021, Dr. Johnson recorded that plaintiff had "new and worsening pain in his lumbar spine" and "recently had a return of pain radiating down his leg." *Id.* at 58. After ordering new MRI scans, Dr. Johnson noted on July 16, 2021 that plaintiff's "hardware is unchanged" and that "[t]here is no neural impingement through the region of his previous surgery or at the other levels of the lumbar spine." *Id.* at 63. On January 7, 2022, Dr. Johnson's physician's assistant recorded after an office visit that plaintiff's "symptoms are unchanged" and that "[i]t is likely that this will be his lifelong situation and he is aware of that." *Id.* at 65.

Plaintiff initiated this lawsuit in the Multnomah County Circuit Court on December 11, 2020, asserting that the AccuLIF TL interbody device was defective. Defendant subsequently removed the case to this Court on January 19, 2021. Before the Court are defendant's three motions in limine, seeking to exclude expert reports and testimony by three of plaintiff's expert witnesses, as well as the parties' cross-motions for summary judgment. Because defendant's motions in limine have bearing on the motions for summary judgment, they are considered first.

DISCUSSION

A. Motions in Limine

Defendant filed three motions in limine to exclude the testimony of (1) Dr. Johnson, who offered expert testimony on medical causation; (2) Mari Truman, who offered expert testimony on design defect and failure to warn; and (3) John Cary, who offered expert testimony on damages. The basis of each of defendant's motions is FRE 702, which governs the admissibility of expert testimony.[2]

Analysis of an FRE 702 objection begins with the standard set forth by the Supreme

[2] Although defendant removed this case based on diversity jurisdiction, the admissibility of evidence is governed by federal law because a court sitting in diversity applies state substantive law, but federal procedural law. *Primiano v. Cook*, 598 F.3d 558, 563 (9th Cir. 2010).

Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc*. 509 U.S. 579 (1993). Under *Daubert*, this Court has a "gatekeeping role" to ensure that expert testimony is both relevant and reliable. *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1043 (9th Cir. 2014). Relevancy is determined by assessing whether "the knowledge underlying [the testimony] has a valid connection to the pertinent inquiry." *Daubert*, 509 U.S. at 565. Reliability is determined by assessing whether "the knowledge underlying [the testimony] has a reliable basis in the knowledge and experience of the relevant discipline." *Id.* The key inquiry for a reliability assessment is "whether the reasoning or methodology underlying the testimony is reliable . . . [and] whether that reasoning or methodology properly can be applied to the facts in issue." *United States v. Hermanek*, 289 F.3d 1076, 1093 (9th Cir. 2002) (internal quotation marks omitted). The reliability test is flexible, permitting a court to assess an expert's reasoning or methodology using appropriate criteria "such as testability, publication in peer-reviewed literature, known or potential error rate, and general acceptance." *City of Pomona*, 750 F.3d at 1044. However, in its gatekeeping role, a court is not "deciding whether the expert is right or wrong, just whether his testimony has substance such that it would be helpful to a jury." *Alaska Rent-A-Car, Inc. v. Avis Budget Group, Inc.*, 738 F.3d 960, 969-70 (9th Cir. 2013). Thus, "[s]haky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Daubert*, 509 U.S. at 564.

Although *Daubert* dealt with expert scientific testimony, the same standards apply to expert *specialized* testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Although the same factors utilized in a *Daubert* assessment are applicable to specialized testimony, rigid application of the *Daubert* factors is not required. *City of Pomona*, 750 F.3d at 1044. Instead, only factors that bear on, or are applicable to, the basis for the testimony need to be examined. *Id.* Thus, this Court has "broad latitude in determining the appropriate form of the inquiry" when assessing the admissibility of expert specialized testimony. *United States v. Valencia-Lopez*, 971 F.3d 891, 898 (9th Cir. 2020).

1. *Dr. Johnson's Testimony*

Plaintiff offers Dr. Johnson's expert testimony to establish the medical causation portion of his claim. Dr. Johnson is a neurosurgeon who has been practicing in this specialty since 1997. Dr.

Johnson has also been plaintiff's provider since April 2016, and was the surgeon who implanted the AccuLIF TL device in plaintiff's spine. Defendant argues that Dr. Johnson's testimony and expert report should be excluded because he has no expertise in mechanical design or manufacturing, his expert opinions on causation are not based on a reliable methodology, and Dr. Johnson's opinions differ from those he expressed during plaintiff's treatment.

Dr. Johnson expert report contains the follow conclusion:

> "[T]he failure of the interbody device is clearly an important contributing factor. It was the primary factor that led to the second surgery. I do think that [plaintiff] would be in better shape if the device would have worked properly. The failure of the expandable interbody cage was the major cause of his current disability."

Def.'s Amended Mot. in limine to Exclude Testimony of Dr. Johnson ("Def.'s Mot. to Exclude - Dr. Johnson"), ECF [37], Ex. B, at 6. Dr. Johnson's expert report states that he "formed these opinions from [his] records and recollections of [his] care for [plaintiff] as his surgeon, as well as [his] general knowledge and experience as a neurosurgeon." *Id.* at 1.

Although Dr. Johnson's expert report provides little detail regarding how he determined that the cage collapse contributed to plaintiff's pain, he expanded on this conclusion during his deposition. When asked how the cage collapse could generally cause pain, Dr. Johnson stated, "[T]he obvious ways would have been, one, if the cage was somehow impacting the nerve root. And I didn't really think that was going to be the case, and I didn't think so on the surgery[.]" *Id.* at Ex. C, at 130:3-6. Additionally, Dr. Johnson stated, "[T]he other way is that when you lose height, . . . you're no longer distracting the spine at that level. . . . [T]hat is visible on the films . . . [s]o that's a reasonable thing to assume could be contributing to his pain." *Id.* 130:8-15. Importantly, Dr. Johnson noted, "I also would say that [plaintiff's] pain was much more diffuse than a simple one nerve root or one level nerve root compression, but it seemed like it could have been part of the picture." *Id.* 130:16-19. Dr. Johnson subsequently clarified that the nerve compression "was the cause of [plaintiff's] problem" to a reasonable degree of medical certainty. *Id.* 130:24-131:1.

However, when asked about his methodology and process for deriving his conclusions,

Dr. Johnson's explanation raises concerns. The following excerpts from his deposition are informative:

> "Q. Is it possible to say to a reasonable degree of medical certainty whether [plaintiff's] outcome would have been different if the cage had not collapsed?
> "A. It's hard to say. I do believe that he would have done better if it had not collapsed.
> "Q. Is that to a reasonable degree of medical certainty?
> "A. Yes.
> "Q. And how do you – how do you form that opinion?
> "A. I don't know. Like I say, it's a tough assessment. It's just my sense.
> "Q. Is there any . . . objective or even subjective methodology that we can look to?
> "A. No.
> "Q. Okay. Just your gut says he might have done better?
> "A. Yes."

Id. 123:6-22.

> "Q. But you've done this before. You understand that the big question is what methodology did you use to arrive at that –
> "A. There's no methodology, sir. I'm sorry."

Id. 192:6-9.

> "Q. Okay. And what about the continued observation of [plaintiff] has led you to conclude that the cage collapse was actually the major cause of his ongoing pain?
> "A. Just the entire clinical picture.
> "Q. Can you get specific? I really need to know what your methodology has been.
> "A. I don't have a methodology. I just have my instincts as a clinician."

Id. 248:18-249:1. Based Dr. Johnson's own admissions, it appears clear that he utilized no generally accepted methodology in arriving at his medical conclusions. Plaintiff, however, rejects this conclusion, arguing that Dr. Johnson's testimony is based on his methodology of making a clinical diagnosis, similar to the expert's process in *Sullivan v. United States Department of the Navy*. 365 F.3d 827 (9th Cir. 2004). To some extent, Dr. Johnson's opinions could be construed as a methodology of applying scientific principles because he relied on his experience as a neurosurgeon to assess the ways that the cage collapse could have caused plaintiff's pain.

It is true that medical clinicians may proffer reliable expert testimony even when derived from their own experience. However, in such cases, the experts had extensive experience with the type of issue that their opinion discussed. For example, in *Sullivan*, the expert who provided an opinion on the cause of the plaintiff's wound complication had extensive experience with patients who received the exact

type of surgery that the plaintiff had received, the alleged cause of the injury was a common occurrence in the medical field, and the expert's conclusions were supported by objective evidence from four textbooks. *Id.* at 830. Similarly, in *Messick v. Novartis Pharmaceuticals Corporation*, the expert who provided an opinion on the causal link between the plaintiff's bisphosphonate treatment and later development of bisphosphonate-related osteonecrosis of the jaw ("BRONJ") had extensive experience diagnosing and treating osteonecrosis of the jaw, including in patients who had been treated with bisphosphonates like the plaintiff. 747 F.3d 1193, 1196 (9th Cir. 2014). Although the plaintiff's injury was not derived from a common cause, the expert's experience included treating patients who had experienced the exact problems that the plaintiff was facing.

In this case, Dr. Johnson's clinical experience does not contain the same breadth of knowledge. As he stated in his own expert report, "[plaintiff] is the only patient of [his] who experienced this problem to [his] knowledge." Def.'s Mot. to Exclude – Dr. Johnson, Ex. B, at 2. Thus, it is difficult to parse how Dr. Johnson's experience, standing alone, could support his opinion that the cage collapse was a substantial factor in plaintiff's pain when, by his own admission, Dr. Johnson has no experience with an expandable cage collapsing. This is not an instance where Dr. Johnson is applying a broader scientific principle as a surgeon experienced in his field. Indeed, he has, admittedly, no experience with the potential impacts of a cage collapse.

Plaintiff argues that Dr. Johnson's opinion is supported by objective evidence because he relied on multiple radiological films, FDA reporting records, and his own medical records. However, radiological films, FDA reporting records, and medical records are not analogous to the type of objective evidence typically viewed as substantiating an expert's opinion. In *Sullivan*, the expert relied on textbooks to support her opinion that the length of a surgery may bear on the likelihood of infection. 365 F.3d at 831. In *Messick*, the expert relied on the American Association of Oral and Maxillofacial Surgeons definition of BRONJ to reach his diagnosis and causation conclusions. 747 F.3d at 1198. Although medical records may, in some circumstances, *support* a clinician's overall conclusion, they do not independently *verify* the methodology that the clinician used. That is, while a medical record may be

the basis of an expert's findings, it offers no explanation for the validity of the expert's methods. To be sure, peer-reviewed literature supporting an expert's conclusion is not always required. *See Primiano*, 598 F.3d at 566 (noting that *Daubert* offers "several reasons why an opinion unsupported by peer-reviewed publication may be admissible"). However, it is still relevant to the overall reliability of Dr. Johnson's methods, and Dr. Johnson's inability to provide an objective basis substantiating his applied principles, is, at a minimum, concerning. *See Lust ex rel. Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 597-98 (9th Cir. 1996) (affirming exclusion of expert report where expert did not provide "an objective source demonstrating that his method and premises were generally accepted by or espoused by a recognized minority" in his field).

Additionally, it is difficult to see how Dr. Johnson's medical records could support his expert opinions. His records indicate that his review of the 2018 MRI scan found no "neural impingement in any location, particularly at the L4-5 level." Def.'s Mot. to Exclude – Dr. Johnson, Ex. D, at 28. In his records, he stated that "it [was] unclear whether [the cage collapse] [was] responsible for [plaintiff's] symptoms." *Id.* 32. When Dr. Johnson performed the reoperative surgery, he confirmed that "the cage was not directly touching or compressing the L5 nerve root." *Id.* Ex. B, at 5. Similarly, prior to the reoperative surgery, Dr. Johnson had considered whether the height loss on the cage could be "causing foraminal stenosis and compression of both left L4 nerve roots"; however, he noted that "[plaintiff's] symptoms were more diffuse." *Id.* Even during the reoperative surgery when Dr. Johnson noted that the L4 nerve root was "moderately compressed," he stated only that it was "possibly indicative of [ ] being a source of [plaintiff's] pain." *Id.* 17-18.

Further, Dr. Johnson's records include his own statement that the "change in the interbody cage" was "of questionable significance." *Id.* Ex. D, at 28. In part, Dr. Johnson had considered the change of questionable significance because a solid fusion had still occurred.[3] *Id.* Yet, in his deposition,

[3] In a successful spinal surgery, the patient will typically have a bone formation that fuses (or creates a union) to the implanted cage to the vertebrae that is implanted between. Mount Sinai, *Spinal Fusion*, https://www.mountsinai.org/health-library/surgery/spinal-fusion (last visited October 11, 2023). Nonunion occurs when a fusion fails to form, and can be attributed to a variety of factors such as "excessive motion at the fusion site,

Dr. Johnson asserted that, in his prior records, he was merely expressing an "opposing viewpoint or the contrary position" because he was trying to "explore all aspects" of plaintiff's pain. *Id.* Ex. C, at 126:6-14. Put another way, Dr. Johnson asserted that his prior records and his current report were not at all contradictory because his records reflected his opinion in a "clinical report," whereas his expert report considers his records in a "legal report."[4] *Id.* 131:20-24. That is, Dr. Johnson asserted that his letter stating that the cage collapse was of "questionable significance" was not written in a context of "assigning blame to one thing or another." *Id.* 136:23-24. However, Dr. Johnson admitted that the letter was "looking at the various factors and determining . . . what is to blame[.]" *Id.* 137:3-6. In essence, far from supporting a finding that the cage collapse was a substantial factor in plaintiff's pain, Dr. Johnson's medical records reveal a consistent uncertainty regarding whether the cage collapse was even *a* cause of plaintiff's pain.

On one hand, the discrepancies in Dr. Johnson's records and his expert report could be more properly assessed through cross-examination or impeachment. *See Alaska-Rent-A-Car*, 709 F.3d at 882. However, in the context of Dr. Johnson's proffered expert testimony as a whole, the discrepancies contribute to the overarching theme of unreliability. If plaintiff's argument is that Dr. Johnson's expert opinion was formed through "a clinical diagnosis," then it is difficult to reconcile how Dr. Johnson could initially find the cage collapse to be of "questionable significance" precisely because plaintiff's symptoms were more widespread, but later render an expert opinion stating that the cage collapse was a substantial factor in plaintiff's symptoms.

Finally, the reliability of Dr. Johnson's methodology is concerning in light of the unique facts of this case. Prior to the surgery, plaintiff already had a history of chronic back and leg pain, including a "bilateral foraminal narrowing with L4 nerve root impingement within the foramina." *Id.* Ex. D, at 2. Given that the only scientific principle that this Court can identify in Dr. Johnson's proffered

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metabolic abnormalities, smoking, trauma, infection, and poor surgical technique." Cathy Lee, Job Dorcil, & Timothy E. Radomisli, *Nonunion of the Spine: A Review*, 419 CLINICAL ORTHO. & RELATED RES. 71, 71-72 (2004).

[4] This statement is particularly concerning given that opinions formed "expressly for the purposes of testifying" are viewed unfavorably. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

testimony is in his opinion that the cage collapse could have caused a nerve impingement at the L4 nerve root, the fact that plaintiff already had such an issue prior to the surgery is significant. Yet, as defendant notes, Dr. Johnson did not use a differential diagnosis to assess and reject alternative causes.[5] Indeed, it does not appear that Dr. Johnson assessed alternative causes at all in forming his opinions.

To be fair, in the medical context, the Ninth Circuit has noted that an expert is not required "to identify the sole cause of a medical condition in order for his or her testimony to be reliable. It is enough that a medical condition be a substantial causative factor." *Messick*, 747 F.3d at 1199. In part, this is because "causation can be proved even when we don't know precisely *how* the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage *somehow*." *Id.* at 1198.

However, as already stated, the issue with Dr. Johnson's opinions is not that he fails to identify a single cause; rather, it is his failure to explain how the cage collapse could be a substantial factor in light of the numerous possible factors causing plaintiff's pain. That is, while his opinion could support a finding that the cage collapse was *a* factor in plaintiff's pain, Dr. Johnson's lack of analysis of alternative contributing causes seriously undermines his finding that the cage collapse was a *substantial* factor. As Dr. Johnson acknowledged, plaintiff's pain was "much more diffuse than a simple one nerve root or one level nerve root compression" and "[i]t's hard to make a direct connection and say this matches [plaintiff's] pain perfectly because his symptoms area so widespread, diffuse, *unchanged*." Def.'s Mot. to Exclude – Dr. Johnson, Ex. C, at 125:6-8, 130:16-19 (emphasis added). Dr. Johnson seems to recognize that the cage collapse could not account for the magnitude of pain that plaintiff was experiencing, and that plaintiff's recurrence of pain mirrored his pre-surgery pain. Yet Dr. Johnson attempts to assert that the cage collapse was, nevertheless, a substantial causative factor of plaintiff's pain

[5] Differential diagnosis is "the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings." *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003) (internal quotation marks omitted). Put another way, it is a "standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999).

without examining or considering the impact of the myriad of other factors affecting plaintiff's pain. Put simply, Dr. Johnson deemed the cage collapse a "substantial factor" without providing any analysis or even reference to the question of whether the cage collapse was a cause of plaintiff's pain, or if the collapse simply failed to remedy plaintiff's pain.[6] Although excluding potential causes may be difficult due to the "difficulties in establishing certainty in the medical sciences," an expert opinion that wholly fails to consider alternative causes cannot be a reliably based opinion. *See Messick*, 747 F.3d at 1198 (noting that "experts must provide scientifically sound reasons for excluding potential causes").

In sum, Dr. Johnson's experience may qualify him as an expert; however, his determination that the cage collapse was a significant contributing factor in plaintiff's pain is unreliable because he provided no objective basis for that conclusion, his conclusion is unsupported by the evidence he relies upon, and he provided no analysis of alternative factors when determining the cage collapse was a significant contributing factor. Therefore, defendant's Amended Motion in limine to Exclude Dr. Johnson's Testimony is GRANTED.

2. *Mari Truman's Testimony*

Plaintiff offers Truman's expert opinion to establish whether the AccuLIF TL implanted in plaintiff was defective. In sum, Truman's expert opinion is that: (1) the AccuLIF TL cage was not designed to be strong enough to be used under reasonably anticipated loads and was dangerous and unsuitable for its intended purpose; (2) the AccuLIF TL cage is defective in design because the harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design; (3) reasonable alternative devices were available that were stronger in dynamic loading without risk of collapse; (4) the warnings provided at the time of plaintiff's surgery did not provide sufficient information regarding the capability of the cage, its risk of collapse, or related complications in higher

[6] This is particularly concerning given Dr. Johnson's numerous medical records describing plaintiff's pain as similar, or the same, as his pre-surgery complaints. *See* Def.'s Mot. to Exclude – Dr. Johnson, Ex. D, at 8 ("There has been little change in [plaintiff's overall pain picture. He still has left-sided back and leg pain, which is fairly diffuse."); *id.* at 18 (describing plaintiff's pain as "primarily axial" and "associated with poor outcome from surgery"); *id.* at 20 (noting that plaintiff described pain as "essentially returned to *where it was before the surgery*" and describing pain as following "much the same pattern as it always has" (emphasis added)).

demand patients; (5) the warnings provided were insufficient and defective because they provided no notice of the risk of collapse; and (6) plaintiff did not act unreasonably to cause the cage collapse. Truman is a biomedical engineer with forty-two years of experience in biomechanics and orthopedics fields.[7] Through her experience, Truman "routinely deal[s] with forces that are applied to the human body during many activities, including impact and injury scenarios." Def.'s Mot. in limine to Exclude Testimony of Truman ("Def.'s Mot. to Exclude – Truman"), ECF [38], Ex. B, at 3. Further, her work involves defining clinically relevant performance requirements for the installation and use of medical devices and test such products to assess the specific performance characteristics.

Defendant argues that Truman's expert report and testimony are unreliable because (1) Truman has no data to support her expert opinions on defective design; (2) Truman bases her defective warning opinions on irrelevant and incomplete data; and (3) as a biomedical engineer with no medical training or degree, Truman is unqualified to testify regarding the medical causation of plaintiff's injuries.

a. Design Defect

As stated in her expert report, Truman's expert opinion on the design defect issue is that:

> "Due to failure of CoAlign and Stryker to design an expandable cage strong or fail-safe enough to be used under reasonably anticipated loading without collapse, [plaintiff] was exposed to the hazards of premature implant collapse, posterior device migration, increased L4-L5 listhesis (slip), nerve compression injury, relapse of presurgery pain and functional limitations by 6 months post op, persistent, severe and debilitating symptoms for another 2 years (December 2016 to February 2019), followed by a second surgery too [*sic*] correct, and prolonged physical therapy to recover his lost function and to reduce related pain symptoms. The combination of the hazard and exposure makes this product dangerous and unsuitable for its intended purpose."

Id. at 52. Put simply, Truman's opinion is that the AccuLIF TL cage implanted in plaintiff was defective because it could not withstand the forces exerted by the lumbar spine during daily living activities. To reach this conclusion, Truman relied on dynamic compression shear tests that were performed on

[7] Biomechanics is a sub-specialty field of bioengineering, and orthopedic biomechanics is a further sub-field which involves the application of principles of engineering mechanics to understand basic biological processes and mechanisms related to the structure and function of bone and other skeletal tissues.

AccuLIF TL devices and AccuLIF PL devices between 2009 and 2016.[8] Prior to examining Truman's expert opinions from her review, it is helpful to provide an overview of the relevant testing parameters of medical devices like the AccuLIF TL device. The AccuLIF TL device at issue in this case was submitted to the FDA through the premarket 510(k) process, meaning that it was marketed as safe and effective because it was substantially equivalent to a legally marketed device (commonly known as a "predicate" device).[9] Substantial equivalence always requires that the offered device has the same intended use as the predicate device; however, if the offered device has different technological characteristics that do not raise different questions of safety and effectiveness, the FDA reviews the performance data and scientific methods used to evaluate the differences in technological characteristics to determine if the device is as safe and effective as the predicate device. This usually includes engineering performance testing, which is the type of testing that Truman reviewed in her report.

FDA guidance on Class II interfusion body devices, like the AccuLIF TL device, recommends mechanical testing for the "worst case" final design version.[10] *See* U.S. FOOD & DRUG ADMIN., INTERVERTEBRAL BODY FUSION DEVICE – CLASS II SPECIAL CONTROLS GUIDANCE FOR INDUSTRY AND FDA STAFF 10 (2007). The FDA generally recommends using different ASTM testing parameters to determine the safety and efficacy of a proposed device. *Id.* 10-11. For static and dynamic testing, the FDA recommends the ASTM F2077-03. *Id.* ASTM F2077 standards set forth several tests, including compression, compression shear, and torsional in both static and fatigue modes. As relevant to Truman's motion, an interbody fusion device meets the ASTM F2077 compression shear test requirements if it attains five million cycles of 1,000 N of dynamic compression shear force without functional failure. Def.'s Reply to Mot. in limine to Exclude Testimony of Truman, ECF [53], Ex. B,

[8] Defendant describes a dynamic compression shear test as a test "designed to apply stress to a test sample to determine the stiffness or resistance of the test sample to deform under loading." Def.'s Mot. to Exclude – Truman 12 n.10. The test is performed through "shear forces caus[ing] one surface of a material to move in one direction and the other surface to move in the opposite direction so that the material is stressed in a sliding motion." *Id.*

[9] The alternative to a 510(k) submission is the more rigorous premarket approval process, which requires a device "to be made with almost no deviations from the specifications in its approval application[.]" *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 416-17 (2008).

[10] A "worst case" final design version is, essentially, the design version that is most likely to fail.

at 117:9-118:23. As the Court understands the term, functional failure means a failure that renders the device no longer suitable for its intended purpose.

Turning back to Truman's report, based on dynamic compression shear tests conducted on various AccuLIF TL models between 2009 and 2016, Truman concluded that an older version of the AccuLIF TL device, which she asserted was most likely used in plaintiff's surgery, "had a dynamic compressive shear 5 [million cycles] runout of 1000 N (224.8 lb)." Def.'s Mot. to Exclude – Truman, Ex. B, at 35. Truman stated that 1,000 N was below the "documented lumbar spine anterior column loading in many individuals" because "[f]orce is generally proportional to patient weigh[t] and varies with activity." *Id.* at 32. In lieu of 1,000 N, she asserted that 2,000 N was a more acceptable benchmark for a device intended for use in the lumbar spine. *Id.* Ex. C, at 93:18-22.

Additionally, Truman referenced AccuLIF's complaint history from December 2014 which documented three collapses.[11] She also searched the FDA's Manufacturer and User Facility Device Experience ("MAUDE") from January 1, 2014, through June 30, 2022 and noted ninety-three medical device reports for the AccuLIF TL device, seventeen of which were for collapse and nine of which were for migration. Prior to plaintiff's surgery, sixty-seven medical device reports for the AccuLIF TL device were documented, six of which were due to collapse and four due to migration. Ultimately, Truman concluded that the AccuLIF TL was defectively designed because it could not withstand 1,000 N of dynamic compression shear force.

Defendant argues that Truman's expert opinion is unreliable under *Daubert* because (1) she did not testify regarding any specific design parameters that would have produced an expandable device strong enough to withstand a cage collapse; and (2) she completed no testing on the AccuLIF TL model that was implanted in plaintiff and has no data on its actual strength. Therefore, defendant argues that Truman's opinion that defendant did not "design an expandable cage strong or fail-safe enough to be used under reasonable anticipated loading without collapse" should be excluded. *Id.* Ex. B, at 53.

[11] It is unclear from Truman's report which AccuLIF TL device received these complaints, or if the devices complained of were the same model as the one used in plaintiff's surgery.

Truman did identify a design parameter that would have made the AccuLIF TL strong enough by asserting that a device that could withstand 2,000 N of dynamic compression shear force would have created a safer design. Although she did not perform her own tests to determine if 2,000 N was a safe amount of force, Truman included an appendix to her expert opinion that discusses the force loads that are commonly exerted by the spine. That appendix relies on numerous outside studies and research, much of which appears to be peer-reviewed. Given Truman's extensive background in determining the impact of forces exerted on the body, as well as the objective bases supporting her conclusion that 2,000 N of force is an appropriate measure of a cage's ability to withstand spinal forces, her proffered opinion is reliable.

Defendant also argues that Truman's proposed benchmark is inadmissible because it imposes a requirement different than those issued by the FDA and is thus preempted. 21 U.S.C. § 360k(a) (prohibiting states from imposing requirements on devices intended for human use "which are different from, or in addition to, any requirement applicable under this chapter to the device"). However, because defendant first raised this argument in its reply, the Court will not address it.[12] *See Zamani v. Carnes*, 491 F.3d 990, 997 (9th Cir. 2007) ("The district court need not consider arguments raised for the first time in a reply brief.").

Although Truman's expert opinion regarding the amount of force a device like the AccuLIF TL should be able to withstand to be safe for use in the general population is based upon reliable principles, the Court is not convinced that she has reliably applied that opinion to the facts of the case. In reaching her conclusion that the AccuLIF TL could not withstand 2,000 N of dynamic compression shear force, Truman relied on six reports of clinical failures of the AccuLIF TL device where the cage collapsed. However, she conducted no inquiry into those reports to determine *why* the cages collapsed in those cases. *See* Def.'s Mot. to Exclude – Truman, Ex. C, at 158:7-19. That is, she had no context for

[12] In any event, this argument lacks merit. Supreme Court case law is clear: devices approved through the 510(k) process do not have FDA imposed requirements regarding their design, and design-defect claims brought against 510(k) approved devices are not preempted. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493-94 (1996).

what amount of force was exerted on the devices in those cases, nor could she provide even an estimate of the amount of force because she did not know the patients' weights, ages, activity levels, etc. In essence, she assumed without assessment that the collapses occurred due to a design defect.

Second, Truman conducted no testing on the AccuLIF TL model that was actually implanted in plaintiff.[13] In failing to do so, she ultimately relied on testing conducted by the manufacturer that was intended to meet the *minimum* threshold of compliance, not the device's maximum capabilities. *See id.* 129:4-11. Truman did not assess whether the device was capable of withstanding a force of 2,000 N before making her conclusion that it was defective for failing to meet 2,000 N. Nor could Truman base her defective assessment on the load that plaintiff exerted on his device, because, as she stated in her deposition, she did not know what amount of force he put on the device. *Id.* 122:24-123:2.

In essence, Truman's opinion is that because the AccuLIF TL failed under 1,000 N of dynamic compression shear force, it was defectively designed. However, the "failure" that Truman relies on was breakage at the bottom plate, not a cage collapse. *See id.* Ex. B, at 32-36. As Truman acknowledged in her deposition, the devices "pass[ed] the functional requirement in that [they did not] have a catastrophic collapse." *Id.* 122:11-14. Truman's report contains no information regarding what level of force can be exerted on the AccuLIF TL before it becomes nonfunctional or collapses. In her deposition, the only evidence she pointed to was the fact that the cage had collapsed in plaintiff. *Id.* 104:2-7. Yet, she admittedly does not know, and does not estimate, what amount of force plaintiff exerted on the device. Further, she acknowledged that "when you look at an individual patient, you can't say what that force was that caused it to fail in that specific situation." *Id.* 107:20-24. Thus, it is entirely unclear on what basis Truman makes the leap from breakage to a cage collapse when she has no evidence of what amount of force will cause the cage to collapse. In this respect, her opinion is wholly speculative.

On one hand, pre-existing data regarding what amount of force was necessary to cause the AccuLIF TL to collapse was not readily available because the FDA does not require testing on

[13] It is unclear to the Court whether manufacturer testing data was available to Truman for the specific model of the AccuLIF TL device that was implanted in plaintiff.

maximum loads. Further, it is not entirely clear if any test data is available for the specific AccuLIF TL model implanted in plaintiff. However, Truman stated in her deposition that she could have conducted testing on the AccuLIF TL device that was implanted in plaintiff but chose not to do so due to the financial cost. *Id.* 278:23-279:13. Nor did she request access to the devices through plaintiff's attorney. *Id.* 279:14-16. The fact that Truman could have conducted testing on the AccuLIF TL model that was implanted in plaintiff to provide an objective basis for her opinion, yet chose not to, deeply undermines the reliability of her opinion. *See Daubert*, 509 U.S. at 593 (discussing testability as a key question in reliability analysis). While the Court recognizes the significant costs inherent in retaining experts, hardship cannot be used to justify an otherwise unreliable application of scientific principles. Truman had the means and ability to test her conclusion but chose not to.

Plaintiff argues, however, that Truman's lack of knowledge about the load-bearing strength of the cage system that plaintiff received, is an issue that go the weight of her testimony, not its admissibility. Plaintiff points to expert testimony offered in car crash cases, where the Oregon Court of Appeals determined that specialized testing is not necessary to determine if a "particular individual would be injured in a particular collision" if the data from already conducted crash tests were reasonably applied to perform a "biomedical injury assessment analysis." *Durette v. Virgil*, 272 Or. App. 545, 556, 356 P.3d 639 (2015).

Plaintiff's reference to Oregon case law is unavailing because a district court sitting in diversity must apply state substantive law but abides by federal procedural law. *Primiano*, 598 F.3d at 563 ("The question whether evidence is admissible . . . is governed by federal law."). Although there are exceptions to this general rule, plaintiff has pointed to none in this instance. *See Wray v. Gregory*, 61 F.3d 1414, 1417 (9th Cir. 1995) (discussing application of state evidentiary provisions when state evidence rule is "intimately bound up with the rights and obligations being asserted" (internal quotation marks omitted)). Further, the issue identified by this Court is not whether a "particular individual" would have been injured by the cage collapse; the issue is whether Truman has a basis for her proposition that the AccuLIF TL would collapse under 1,000 N of force. Truman has not asserted, or provided support

for, her assumption that a cage that exhibits breakage under 1,000 N of force will also collapse under 1,000 N of force. In short, the reliability of Truman's proffered testimony hinges on whether she utilized an adequate methodology to arrive at her conclusion that the AccuLIF TL cage is defectively designed because it cannot withstand 2,000 N of dynamic compressive shear force without collapsing. She has not. Therefore, her expert opinion that the AccuLF TL cage was defectively designed because it could not withstand 2,000 N of dynamic compression shear force without collapsing is unreliable and inadmissible.

b. Reasonable Alternative Design

Truman's reasonable alternative design opinions are that:

> "The AccuLIF TL spinal interbody implants are defective in design in that the harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer, and the omission of that alternative design rendered this product unsafe.
>
> "There are reasonable alternative devices that are stronger in dynamic loading without risk of collapse (or a [*sic*] for monolithic devices, without risk of a similar height reduction due to a catastrophic break), and thus have reduced risk of related adverse effect such as posterior device migration into the neural canal, loss of foramen height, nerve root compression and relapse of pre-index surgery conditions as occurred in [plaintiff]."

Def.'s Mot. to Exclude – Truman, Ex. B, at 53. Defendant argues that these opinions are unreliable because Truman does not specifically identify a "more durable alternative," and because the study that she relied upon specifically excluded expandable cages in its analysis. Further, defendant notes that the strength of the static cages assessed in the study was based on the maximum load that the devices withstood in the testing that was submitted to the FDA.

Under Oregon law, a plaintiff may establish consumer expectations in a design defect claim by proving "that a product could have feasibly and practicably been designed more safely." *McCathern v. Toyota Motor Corp.*, 332 Or. 59, 76, 23 P.3d 320 (2001). In part, this requires an assessment of whether the alternative design could "eliminate the unsafe characteristic of the product without impairing its usefulness or making it too expensive." *Wood v. Ford Motor Co.*, 71 Or. App. 87, 91, 691 P.2d 495 (1984); *see Glover v. BIC Corp.*, 6 F.3d 1318, 1331 (9th Cir. 1993).

In assessing safer alternative designs, Truman relied on a 2018 article (the "Peck

Article") that reviewed 124 lumbar intervertebral fixation devices approved through traditional 510(k) submissions to the FDA from 2007 through 2016. The article provided the mechanical test results for seven of the commonly performed tests, including the dynamic compression shear test. The specific brand names and manufacturers of the devices included in the study were not provided. Notably, the study states that it is "limited to single-piece L-IBFDs without integrated fixation, *expandable features*, or coatings[.]" *Id.* Ex. G, at 2 (emphasis added). Additionally, Truman relied on the FDA Draft Guidance for Spinal Device Testing from May 2004 (the "FDA Draft Guidance"), which recommended that individual monolithic cages be able to withstand 1,500 N for ten million cycles and 3,000 N for five million cycles.

Truman's methodology for identifying safer alternative designs raises concerns. Both the Peck Article and the FDA Draft Guidance that Truman relied upon were limited to monolithic, or static, cages. Thus, they provide little information about whether there is a safer alternative design for an *expandable* cage.[14] Further, in her deposition, Truman clarified that the "unique risk of collapse" that she identified in the AccuLIF TL was only present when comparing it to monolithic cages. *Id.* Ex. C, at 284:12-24. Specifically, she stated that "other expandables have that same risk." *Id.* 284:13-15. When asked directly in her deposition what a safer alternative design would be, she stated, "The only alternative that I can speak to specifically is a static device[.] . . . I don't have the data on [expandable cages]. . . . I don't have the data to show that there's a product that would withstand this environment on the market." *Id.* 305:12-21.

The alternative designs that Truman identified in the Peck Article lack the same utility as the AccuLIF TL. Truman asserted in her deposition that she made the comparison to static cages because data on expandable cages was unavailable. However, as discussed in footnote 13, the expandable feature

[14] The primary difference between monolithic and expandable cages is simple: monolithic cages are not adjustable in height, whereas expandable cages are. Expandable cages were developed, in part, to address issues observed with static cages. Specifically, expandable cages "would allow insertion of the device in a collapsed form without the need for trialing or vertebral distraction, minimizing the trauma to endplates and theoretically decreasing the risk of implant subsidence while obtaining optimal interbody heights." Hossein Elgafy & Kyle Behrens, *Comparing Expandable and Static Interbody Cages in Lumbar Interbody Fusion*, 9 J. SPINE SURGERY 39, 39 (2023).

provides a unique function, utility, and benefit that is unavailable in static cages. Indeed, Truman notes in her expert report that expandable cage technology was developed "to minimize undersizing of static cages in posterior lumbar interbody fusion (PLIF), and transforaminal lumbar interbody fusion (TLIF)." *Id.* Ex. B, at 25. Thus, using a static cage as an alternative design would wholly eliminate an essential characteristic of the AccuLIF TL's usefulness. *See Wood*, 71 Or. App. at 91. To the extent that Truman identifies static cages as safer alternatives to the AccuLIF TL, her testimony is irrelevant. Further, using data from static cages as a means of identifying a safer alternative design for the AccuLIF TL is unreliable because data from static cages is inapplicable to the AccuLIF TL.

During her deposition, Truman also identified ways that the AccuLIF TL's design could be improved to reduce the risk of collapse that would not impede the utility of the device. *See* Def.'s Mot. to Exclude – Truman, Ex. C, at 306:13-21 (describing improvements as "optimization of the thickness of the features, of the locking mechanism to make it more foolproof, maybe add a secondary lock override"). However, she admitted that she had not performed any analyses to determine if these ideas were actually feasible. *Id.* 307:6-8. That is, she did not create, or identify, a product that incorporates these ideas to demonstrate its feasibility, potential cost, or new risks that it could create. *See Edmons v. Home Depot, U.S.A., Inc.*, No. 09-cv-00987-AC, 2011 WL 127165, at *6-7 (D. Or. Jan. 14, 2011) (excluding expert testimony on alternative design where expert did not develop or test proposed designs). Truman acknowledged that such testing was necessary to determine the feasibility of an alternative design, stating, "I think there are some [changes] that would be feasible, but *you would have to do specific analysis and testing* to be sure that it was appropriate." Def.'s Mot. to Exclude – Truman, Ex. C, at 309:18-310:1. In essence, Truman is providing an opinion that offers little more than "the technical possibility of a safer design." *Glover*, 6 F.3d at 1332 (internal quotation marks omitted). Therefore, her alternative design opinions that are unrelated to static cages are also unreliable.

c. Failure to Warn

Defendant also argues that Truman's expert opinions on warning defects are unreliable because they are speculative and unsupported by sufficiently reliable data. Essentially, Truman asserts

that the warnings (1) should have provided specific guidance on the risk of failure based on specific age and weight ranges; (2) should have specifically warned or indicated that the expansion mechanism may collapse; and (3) should have provided specific guidance on what activities to avoid to prevent overloading the cage.

Under Oregon law, a seller or manufacturer is "required to give warning of a danger when the danger is not 'generally known' and if the seller 'has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge,' of the presence of the danger." *Benjamin v. Wal-Mart Stores, Inc.*, 185 Or. App. 444, 454, 61 P.3d 257 (2002) (quoting *Restatement (Second) of Torts* § 402A cmt. j (Am L. Inst. 1965)). The adequacy of a warning's content depends on whether it is "'comprehensible to the average user and [ ] convey[s] a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.'" *Anderson v. Klix Chemical Co.*, 256 Or. 199, 207, 472 P.2d 806 (1970) (quoting *Spruill v. Boyle-Midway, Inc.*, 308 F.2d 79, 85 (4th Cir. 1962)), *abrogated on other grounds by Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 525 P.2d 1033 (1974), *superseded by statute as recognized in McCathern v. Toyota Motor Corp.*, 332 Or. 59, 59, 23 P.3d 320 (2001). Generally, a warning is inadequate if it is misleading, ambiguous, contains important omissions, fails to reveal the full extent of the dangers, or fails to provide notice that use of the product should be permanently discontinued prior to the patient suffering irreversible injury. *McEwen v. Ortho Pharm. Corp.*, 270 Or. 374, 402-04, 528 P.2d 522 (1974).

As an initial matter, defendant's only argument against Truman's opinion that the warnings should have included the risk of collapse is that the risk of collapse is "obvious" for an expandable cage. However, defendant identifies no issues with *how* Truman derived her conclusion. Rather, defendant's issues arise from *what* Truman is saying. Thus, Truman's expert opinion that the warnings should have included the risk of collapse is an issue that may properly be attacked through cross-examination, but it is not excludable under *Daubert*.

However, Truman's expert opinions regarding warnings on specific age and weight ranges and types of activities are not so cut and dry. In essence, her opinion is that the warnings were

deficient because defendant omitted information regarding the device's limitations in the context of specific weights, ages, and activities. In forming these opinions, Truman reviewed two documents from the AccuLIF TL manufacturer. The first was a brochure that contained important medical information ("IMI") regarding contraindications, cautions, precautions, and choice of implants. The second was a package insert included in AccuLIF TL and PL expandable lumbar interbody cages which contained similar information. In relevant part, the IMI included the following instructions:

> "The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. . . . Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.
>
> "The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. . . .
>
> "Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
>
> . . .
>
> "[T]he surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system."

Def.'s Mot. to Exclude – Truman, Ex. B, at 48-49. Additionally, the adverse effects listed in the IMI included "[d]evice breakage, dislodgement or migration." *Id.* at 49.

Truman's report provided no specificity on what age and weight ranges should have been included in the warnings provided. In her deposition, Truman proposed an age range of "under 40 or under 50." *Id.* Ex. C, at 190:3-4. However, her sole basis for this proposed range was the six clinical failures discussed in Section A.2.a of this opinion, and the cage collapse that occurred in plaintiff. *Id.* 198:9-12. As already discussed, Truman admittedly had no information about the circumstances behind the six clinical failures: she does not know the patients' ages, activity levels, weights, etc. Thus, the clinical failures do not provide a reliable basis for her proposed ranges. Although she has this information about plaintiff, a single example is a scant basis for reliability. Aside from this age range, Truman could not identify any other specific weight or activity level limitations that should have been provided in the warnings, aside from the general proposition that such limitations should have been included.

In the context of her entire report, Truman's opinion that the warnings should have

provided more guidance on the specific weight ranges and activity levels that the device was appropriate for seems to be based on her previously drawn conclusions that the device could not withstand more than 1,000 N of dynamic compression shear force. When asked in her deposition what data she relied on to determine that a warning against younger or heavier patients was necessary, she first pointed to plaintiff's cage collapse, before stating, "[B]ased on the forces we know applied [in plaintiff's case], the device didn't have sufficient strength to endure reasonably foreseeable loads in all situations, in all patients." *Id.* 198:13-18. However, Truman does not know what force was applied in plaintiff's case, a fact already discussed at length by this Court. In essence, it seems that Truman opined that warnings on specific weight ranges and activity levels were needed because of the conclusion that she had already drawn: the AccuLIF TL could not withstand 2,000 N of dynamic compression shear force without collapsing. However, as already discussed at length, that conclusion was reached through unreliable means. Thus, relying on that conclusion as the basis for her warnings opinion inherently renders those opinions unreliable. Therefore, Truman's expert opinions regarding warning defects as related to specific age and weight ranges and activity levels are inadmissible.

d. Medical Causation

Finally, defendant argues that Truman has essentially provided a medical causation opinion because her opinion goes beyond merely explaining the types of forces or injuries that *could* be sustained by an alleged defect, and instead specifically links the alleged defect to the injuries that plaintiff himself claims.

It is undisputed that Truman is not qualified to provide opinions on medical causation. Thus, the only question is whether her opinions implicate medical causation. As a biomedical engineer, Truman is qualified to testify "about the forces generated in [an] accident, explain how the body moves in response to those forces, and thus determine what types of injuries would result from the forces generated." *Smelser v. Norfolk Southern Ry. Co.*, 103 F.3d 299, 305 (6th Cir. 1997). However, she is not qualified to "render medical opinions regarding the precise cause of a specific injury." *Id.* Yet, it appears that is precisely what she did.

In asserting that plaintiff was exposed to the specific types of injuries that he incurred, Truman is presenting an opinion that his injuries were caused by the alleged defect in device. To be sure, Truman reviewed plaintiff's medical history thoroughly; however, she does not possess the requisite knowledge or background to apply her general findings of what injuries *may* occur from a cage collapse to the injuries that allegedly occurred *in this case*. In sections of her report, she provides a general analysis of the injuries that could occur from cage collapses: "instability, device posterior migration and/or breakage with expulsion of fragments which can lead to damage to vessels and neural structures." Def.'s Mot. to Exclude – Truman, Ex. B, at 26. These opinions are reliably based on her knowledge and experience as a biomedical engineer. However, other statements are not of that general nature, such as:

> "From a biomechanical standpoint, the loss of [plaintiff's] cage height combined with the surgical destabilization required for correct and fusion, allowed the implant to shift posteriorly relative to the L4 vertebral body, resulting in an increase in the degree of L4-5 spondylolisthesis, loss of L4 foramen height, particularly in the left side, with neural impingement. The collapse of the cage facilitated the posterior shift. The posterior shift increased the risk of the subsidence, which was also noted in the 15-month post op imaging studies."

Id. at 24. This statement directly asserts that the cage collapse caused a posterior shift, an increase in the degree of L4-5 spondylolisthesis, loss of L4 foramen height, and neural impingement—the precise injuries alleged by plaintiff. Couching this opinion as "from a biomechanical standpoint" does not render it anything other than a medical causation opinion. Therefore, Truman's expert opinions and testimony regarding potential injuries that can occur from a cage collapse are excluded to the extent that they connect the cage collapse to the specific injuries that plaintiff alleges.

In sum, defendant's Amended Motion in limine to Exclude Testimony of Truman is GRANTED in part and DENIED in part.

3. *Testimony of John Cary*

Finally, defendant moves to exclude the testimony of plaintiff's expert on damages, John Cary, arguing that his report and testimony are neither relevant nor reliable because he (1) did not apply a correct measure of damages by failing to differentiate between plaintiff's physical condition immediately before and after the index surgery; (2) ignored key documents and failed to review other pertinent medical

records relating to treatment for injuries other than plaintiff's lumbar spine; (3) made assumptions that bely available evidence, rendering his opinions speculative; and (4) his calculations include mathematical errors and consider irrelevant information.

Cary is a certified rehabilitation counselor and certified disability management specialist who has clinical experience in the medical aspects of disability. As stated in his report, he based his opinions on his "knowledge, training, education and experience, and clinical judgment," as well as his "clinical interview with [plaintiff], [his] thorough review of relevant medical records, and consultation with Adam Wachter, PT, and Jeffrey Johnson, MD[.]" Def.'s Mot. in limine to Exclude Testimony of Cary ("Def's. Mot. to Exclude – Cary"), ECF [34], Ex. C, at 5. Further, Cary states that he utilized the RAPEL methodology to determine plaintiff's earning capacity. *Id.* That methodology is a comprehensive, peer-reviewed model that considers resources and strategies from a variety of sources to determine an individual's earning capacity in light of alleged injuries.[15]

Defendant raises numerous issues with Cary's report, including that he did not account for the fact that plaintiff was permanently disabled for at least two years prior to the surgery where the cage was implanted, that Cary assumed that the surgery would have successfully returned plaintiff to his pre-disability state, and that Cary did not review records from medical providers regarding plaintiff's shoulder injury, post-concussive syndrome, or pain management, asserting instead that those issues had been resolved.

As discussed previously, plaintiff has a history of back problems dating back to when he was eleven years old. However, those problems were exacerbated during a car accident in 2014. That accident caused a rotator tear cuff, a concussion, and increased "constant and severe pain" in plaintiff's back and into his hips and legs, as well as numbness and tingling in his feet and toes. Plaintiff filed for disability with the Social Security Administration on April 8, 2016, alleging disability since June 16,

[15] Developed by Roger Weed, the RAPEL methodology involves a five-step process: (1) rehabilitation plan, (2) access to the labor market, (3) placeability, (4) earnings capacity, and (5) labor force participation. Erin O'Callaghan & Nancy Huizenga, *Life Care Planning – Providing Clarity to Medical and Vocational Needs with Associated Costs*, 25 MICH. DEF. Q. 14, 16-18 (2009).

2014, and was found to be disabled under 20 C.F.R. § 404.1520(g) on April 13, 2018. Def.'s Mot. to Exclude – Cary, Ex. F, at 7. In part, the Social Security Administration determined that plaintiff had the following impairments: "post concussive syndrome; lumbar degenerative disc disease with laminectomy/fusion in May 2016; rotator cuff tear with SLAP procedure for the left shoulder in March 2015." *Id.* at 3.

During his deposition, Cary acknowledged that plaintiff had been granted permanent disability following his 2014 accident. *Id.* Ex. G, at 98:8-15. However, he testified that whether plaintiff suffered functional limitations from the 2014 accidents was "a little bit more difficult to discern." *Id.* 110:12-13. Cary had removed treatment for plaintiff's car accident issues from his life care plan; however, he did not delineate those impairments in his vocational assessment. *Id.* 113:19-22.

In Cary's vocational assessment, he acknowledged that plaintiff had "been unable to sustain gainful work activity since June 2014." *Id.* Ex. C, at 18. However, based on his information gathering, he believed that plaintiff was expected to fully recover functionally from his lower back injury and return to work after his 2016 surgery. *Id.* Thus, the remainder of his assessment of plaintiff's earning capacity is based on the premise that plaintiff would have been functional if the 2016 surgery had been successful. For example, when considering plaintiff's access to the labor market, Cary assessed plaintiff's ability to return to the type of work that he had been employed in prior to the 2014 accident. *Id.* at 19. Presumably, this is because Cary assumed that, if the 2016 surgery had been successful, plaintiff would have been able to return to those types of jobs.

To be sure, Cary's conclusions appear to be drawn from less than thorough records and evidence. However, in *Elosu v. Middlefork Ranch Inc.*, 26 F.4th 1017 (9th Cir. 2022), the Ninth Circuit provided helpful guidance on what constitutes "sufficient facts or data" for an expert to make projections from. In that case, the expert proffered a fire origin and cause report where he hypothesized about potential causes of a fire. *Id.* at 1020. The expert had examined the cabin that burnt down, the evidence of fire movement and oxidation patterns, and reviewed recorded interviews, deposition transcripts, and video footage of the fire. *Id.* at 1026. The district court had excluded the expert's testimony after finding

that his conclusions were "speculative and unsupported by the evidence." *Id.* In part, the district court had noted that the facts underlying the expert's report were susceptible to competing interpretations, that the expert relied too heavily on the plaintiffs' version of events, and that the expert's conclusions conflicted with eyewitness testimony. *Id.*

The Ninth Circuit reversed, holding that the district court had overlooked the scientific analysis that formed the basis of the expert's testimony when excluding his testimony. *Id.* at 1027. That is, the district court had concluded that the expert testimony lacked "sufficient facts or data," but disregarded the foundation of the expert's opinion. *Id.* Further, the court noted that the district court had ultimately been weighing the evidence to discredit the expert's conclusions, which went far beyond the district court's gatekeeping rule. *Id.* In the Ninth Circuit's view, these issues were "matters for impeachment, not admissibility." *Id.* at 1028.

Elosu is instructive in the case before this Court. The alleged errors that defendant highlights in Cary's report are similar to those raised in *Elosu*. Although defendant attempts to construe its argument as asserting that Cary applied the RAPEL methodology erroneously, the true assertion of defendant's argument is that the methodology was applied erroneously because Cary's conclusions are contradicted by evidence on the record. This is an argument better served by impeachment than by exclusion. Perhaps Cary should have looked at additional documents regarding the extent of plaintiff's disability prior to the 2016 spine surgery to determine plaintiff's earning capacity; however, this does not mean that he erroneously applied the RAPEL methodology using the materials that he did review. That is, Cary's conclusions were drawn from a reliable application of a peer-reviewed methodology—whether those conclusions are accurate based on the evidence on the record is a question for the jury, not an assessment this Court can make at the admissibility stage.

Therefore, defendant's Motion in limine to Exclude Testimony of Cary is DENIED.

B. Motions for Summary Judgment[16]

[16] As defendant aptly notes, plaintiff failed to include a certificate of conferral, as required by Local Rule 7-1(a)(3). Although this Court has authority to dismiss plaintiff's motion on this basis, it declines to do so given the efficiency

The parties filed cross-motions for summary judgment, with plaintiff seeking partial summary judgment on his claims aside from a damages calculation and defendant seeking summary judgment on all claims. Plaintiff brings four claims: (1) strict products liability, (2) breach of express warranty, (3) breach of implied warranty, and (4) negligence. Because a product liability civil action "embraces all theories a plaintiff can claim in an action based on a product defect," including negligence and strict liability claims, the parties' motions for summary judgment are considered only as they relate to plaintiff's strict products liability claim. *Brown v GlaxoSmithKline, LLC*, 323 Or. App. 214, 219, 523 P.3d 132 (2022); *see Simonsen v. Ford Motor Co.*, 196 Or. App. 460, 466, 102 P.3d 710 (2004) (noting that product liability civil action embraces all theories claimable in action based on product defect, including "negligence, strict liability, breach of warranty, and fraudulent misrepresentation").

Under Oregon law, a product liability civil action may be brought on three bases: (1) "Any design, inspection, testing, manufacturing or other defect in a product"; (2) "[a]ny failure to warn regarding a product"; or (3) "[a]ny failure to properly instruct in the use of a product." Or. Rev. Stat. § 30.900. The elements of a strict products liability claim are set forth in Oregon Revised Statute ("ORS") § 30.920. Under that statute, liability attaches to a seller or lessor of a product "in a defective condition unreasonably dangerous to the user or consumer" when: (1) "The seller or lessor is engaged in the business of selling or leasing such a product"; and (2) "[t]he product is expected to and does reach the user or consumer without substantial change in the condition in which it is sold or leased." *Id.* § 30.920(1)(a)-(b). Liability attaches even if the seller or lessor "exercised all possible care in the preparation and sale or lease of the product" and even if "[t]he user, consumer, or injured party has not purchased or leased the product from or entered into any contractual relations with the seller or lessor." *Id.* § 30.920(2)(a)-(b). Under the statute, courts are to construe the elements of strict products liability "in accordance with the Restatement (Second) of Torts [§] 402A, Comments a to m (1965)." *Id.* § 30.920(3).

Based on plaintiff's complaint, it appears that his product liability claim is based on four distinct theories: (1) a manufacturing defect; (2) a design defect; (3) failure to warn; and (4) failure to

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in addressing both motions simultaneously.

instruct.[17] Plaintiff alleges strict products liability, as opposed to ordinary products liability, because he argues that the alleged defect in the AccuLIF TL cage made it unreasonably dangerous and unfit for its intended use. Plaintiff seeks partial summary judgment on his products liability claim, arguing that there is no genuine dispute as to a material fact regarding all elements of the claim, aside from the issue of damages. Defendant seeks summary judgment on all plaintiff's claims, arguing that there is no evidence as to defect, causation, or damages. Because the cross-motions for summary judgment address many of the same points and involve the same questions, they are considered together.

At a minimum, to survive summary judgment plaintiff must demonstrate a genuine dispute as to a material fact on the following elements: (1) defect, (2) causation, and (3) damages. The various claims that plaintiff brings are all different theories of establishing a product defect; however, causation and damages are central to each theory. Because plaintiff cannot establish a genuine dispute of material fact regarding causation, summary judgment is appropriate on his claims.

To prove causation, a plaintiff must show that the alleged defect was "a substantial factor in producing the damage complained of." *McEwen*, 270 Or. at 407. The Oregon Court of Appeals has held that "[w]hen the element of causation involves a complex medical question, as a matter of law, no rational juror can find that a plaintiff has established causation unless [the plaintiff] has presented expert testimony that there is a reasonable medical probability that the alleged negligence caused the plaintiff's injuries." *Baughman v. Pina*, 200 Or. App. 15, 18, 113 P.3d 459 (2005). The policy behind this rule is preventing "jurors from speculating about causation in cases where that determination requires expertise beyond the knowledge and experience of an ordinary lay person." *Id.*

Plaintiff's case undeniably involves a complex medical question. Plaintiff has a history of chronic pain predating the 2016 spinal surgery that was significant enough to make him eligible for disability benefits. Yet, the crux of plaintiff's claim is that he endured "years of pain and a second

[17] Aside from plaintiff's complaint, none of plaintiff's pleadings reference a failure to instruct theory. To the extent plaintiff's complaint could be construed to reference the theory, it appears to be absorbed into plaintiff's failure to warn theory. Therefore, the Court considers the failure to instruct theory, as presented separately from the failure to warn theory, abandoned.

operative procedure in 2019" as a direct result of the cage collapse. Pl.'s Mot. for Partial Summ. J., 18. Additionally, plaintiff claims that the cage collapse "denied plaintiff the benefits of spinal distraction" and is "the single most significant factor causing [p]laintiff [*sic*] current pain and disability." *Id.* Distinguishing between whether the cage collapse was a substantial factor in plaintiff's current pain, or whether his current pain is a continuation of his preexisting chronic pain that is unrelated to the cage collapse, is a question best addressed by an expert.

Dr. Johnson's expert report and testimony were plaintiff's sole source of expert testimony on medical causation. In the absence of Dr. Johnson's expert opinions, plaintiff cannot demonstrate a genuine dispute of material fact regarding causation. Therefore, summary judgment on his claims is appropriate. *See Teater v. Pfizer, Inc.*, No. 3:05-cv-00604-HU, 2013 WL 2455995, at *6 (D. Or. June 6, 2013) (granting defendant's motion for summary judgment on strict liability claim where plaintiff failed to provide expert testimony on medical causation); *Edmons*, 2011 WL 127165, at *8 (granting defendant's motion for summary judgment on products liability claim where plaintiff provided no "admissible expert testimony or any other objective sources of proof" on causation issue). Defendant's Motion for Summary Judgment is GRANTED, and plaintiff's Motion for Partial Summary Judgment is DENIED.

CONCLUSION

Accordingly, defendant's Amended Motion in limine to Exclude Testimony of Dr. Johnson, ECF [37] is GRANTED. Defendant's Amended Motion in limine to Exclude Testimony of Truman, ECF [38], is GRANTED in part and DENIED in part. Defendant's Motion in limine to Exclude Testimony of Cary, ECF [34], is DENIED. Plaintiff's Motion for Partial Summary Judgment, ECF [30], is DENIED, and defendant's Motion for Summary Judgment, ECF [35], is GRANTED.

IT IS SO ORDERED.

DATED this 17th day of October, 2023.

Adrienne Nelson
United States District Judge